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| APPLICATION NO.   | FILING DATE         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------------|----------------------|---------------------|------------------|
| 09/889,283  | 02/26/2002          | Jean-Louis Ruelle    | BM45348             | 2510             |
| 37509 7500 08/11/2011<br>DECHERT LLP<br>P.O. BOX 390460 |                     |                      | EXAMINER            |                  |
|   |                     |                      | BASKAR, PADMAVATHI  |                  |
| MOUNTAIN  | 'IEW, CA 94039-0460 |                      | ART UNIT            | PAPER NUMBER     |
|   |                     |                      | 1645                |                  |
|   |                     |                      |                     |                  |
|   |                     |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|   |                     |                      | 08/11/2011          | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@dechert.com

### Application No. Applicant(s) 09/889.283 RUELLE ET AL. Office Action Summary Examiner Art Unit PADMA BASKAR 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 7/13/01. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 25-46 is/are pending in the application. Of the above claim(s) is/are withdrawn from consideration. Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) 25-46 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) biected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No.

Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Praftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date \_\_\_\_\_

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

5) Notice of Informal Patent Application

6) Other:

3. Copies of the certified copies of the priority documents have been received in this National Stage

application from the International Bureau (PCT Rule 17.2(a)).

See the attached detailed Office action for a list of the certified cories not received.

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#### DETAILED ACTION

The preliminary amendment filed on 7/13/01 is entered. Claims 25-46 are pending.

#### REQUIREMENT FOR UNITY OF INVENTION

2. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or or a group of inventions os linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFB 1475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1)A product and a process specially adapted for the manufacture of said product; or
- (2)A product and process of use of said product; or
- (3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4)A process and an apparatus or means specifically designed for carrying out the said process; or (5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).
- Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 25, 27, 29, 31-32, 35 and 40-41, and drawn to polypeptide, fusion protein and a vaccine

(See paragraph # 5).

Group II, Claims, 26, 28, 30, 33 34 and 36-39, and drawn to polynucleotide, expression vector,

host cell and a process for expressing said polynucleotide,

(See paragraph # 5).

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Group III claim 42 and 46 drawn to an antibody and therapeutic composition

Group IV claim 43 drawn to a method of raising an immune response using polypeptide in a mammal.

(See paragraph # 5).

Group V claim 44 drawn to a method of diagnosing a Neisseria meningitidis infection

(See paragraph # 5).

Group VI claim 45 drawn to a method of raising an immune response using polynucleotide in a mammal

(See paragraph # 5).

4. The groups of inventions I-VI listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to polypeptides, nucleic acid and antibody. However, Fussenegger et al 1996 discloses peptidoglycan-linked lipoprotein fragment which is 100% identical to fragment of SEQ.ID.NO:2 as shown below. Therefore, the technical feature of linking groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

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peptidoglycan-linked lipoprotein precursor - Neisseria gonorrhoeae
R; Fussenegger, M.; Facius, D.; Meier, J.; Meyer, T.F.
Mol. Microbiol. 19, 1095-1105, 1996
A. Title: A novel peptidoglycan-linked lipoprotein (ComL) that functions in natural transformation
competence of Neisseria gonorrhoeae.
A; Reference number: S71019; MUID: 96249702; PMID: 8830266
A; Status: preliminary
A; Residues: 1-267 < FUS>
A;Cross-references: UNIPROT:050985
C:Genetics:
A.Cono. comt.
C; Superfamily: conserved hypothetical protein HI0177
F;1-17/Domain: signal sequence #status predicted <SIG>
F;18-267/Product: peptidoglycan-linked lipoprotein #status predicted <MAT>
 Query Match
                           45.7%; Score 122; DB 1; Length 267;
  Best Local Similarity 100.0%;
 Matches 122; Conservative 0; Mismatches 0; Indels 0; Gaps
           24 DKDAQITQDWSVEKLYAEAQDELNSSNYTRAVKLYEILESRFPTSRHARQSQLDTAYAYY 83
           24 DKDAQITQDWSVEKLYAEAQDELNSSNYTRAVKLYEILESRFPTSRHARQSQLDTAYAYY 83
Db
           84 KDDEKDKALAAIERFRRLHPQHPNMDYALYLRGLVLFNEDQSFLNKLASQDWSDRDPKAN 143
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Db 84 KODEKDKALAAIERFRRLHPCHPMMDYALYLRGLVLFNEDOSFLNKLASQDWSDRDFRAN 143

GY 144 RE 145

II Db 144 RE 145
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This application contains claims directed to more than one species of the generic invention.
 These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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SEQ.ID.NOS:2, 4, 6, 8, 10, 12, 14 or 16
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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

6. The species of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed polypeptides, SEQ.ID.NOS:2. 4, 6. 8, 10, 12, 14 or 16 share no common special technical feature because the polypeptides have no common structure (i.e., no common sequence). Fussenegger, 1996 discloses peptidoglycan-linked lipoprotein which is 100% identical to fragment of SEQ.ID.NO:2 as shown below. Therefore, SEQ.ID.NOS:2. 4, 6. 8, 10, 12, 14 or 16 are not so linked so as to form a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature as polypeptide SEQ.ID.NO 2does not define a contribution over the prior art as discusses above. Therefore, unity of invention is lacking among SEQ.ID.NOS:2. 4, 6. 8, 10, 12, 14 or 16.

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Species SEQ.ID.NOS:2. 4, 6. 8, 10, 12, 14 or 16 lack unity of invention because the groups do not share the same or corresponding technical feature.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species (one polypeptide and associated fragments of said polypeptide) and invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma V. Baskar whose telephone number is (571)272-0853. The examiner can normally be reached on Mon-Thu 6 A M-4P M

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully, /Padma Baskar/ Examiner, Art Unit 1645